

FLORIDA | Board of Pharmacy

Meeting Minutes

December 11, 2018

Orlando Marriott in Lake Mary

1501 International Pkwy

Lake Mary, FL 32746

Contact Hotel: 407-995-1100



Jeenu Philip, BPharm
Chair

Jeffrey Mesaros, PharmD, JD
Vice-Chair

C. Erica White
Executive Director

Tuesday, December 11, 2018 at 1:30 PM

Call to Order - The meeting was called to order by the Chair, Mr. Philip, at 1:32 p.m.

Roll Call - Those present during the meeting included the following:

Board Members

Jeenu Phillip, BPharm, Chair
Jeffrey J. Mesaros, PharmD, JD, Vice-Chair
David Wright, BPharm
David Bisailon, Consumer Member
Jonathan Hickman, PharmD
Mark Mikhael, PharmD, Chair
Richard Montgomery, BPharm, MBA
Blanca R. Rivera, MPharm, MBA

Absent:

Gavin Meshad, Consumer Member

Attorneys

Board Counsel:
David Flynn, Assistant Attorney General
Lawrence Harris, Assistant Attorney General

Board Staff:

C. Erica White, Executive Director
Jessica Hollingsworth, Government Analyst II

Mr. Philip recognized Bob Parrado, Michele Weizer, and Debra Glass, former board members, for attending the meeting. He also recognized students from the University of Florida and South University, Michael Jackson from FPA, Gary Daylen from FSHP, Investigative Services staff, and Jessica Presley from FDA, for attending. He then congratulated Mark Whitten on his new role as Bureau Chief.

I. **Rule Hearing on Proposed Rule 64B16-27.797, F.A.C.**

Mr. Flynn provided a brief overview of the rule and purpose for the hearing. He recommended for this to be a discussion item today and for an additional hearing to be held in February. Dr. Mikhael clarified that the rule challenge refers to AnazaoHealth Corporation claiming economic impact. Mr. Flynn informed the board of the correct procedure for when regulatory costs are in excess of \$200,000 in the aggregate of Florida within one year after implementation.

T.J. Morton, Attorney for AnazaoHealth Corporation, introduced himself, Rachel Pontikes, Attorney, and Bob McKenzie and Dennis Davis, with AnazaoHealth. He then provided a brief

explanation of the effects the rule change would have on AnazaoHealth and that the rule was being challenged based on failure to complete a statement for estimated regulatory costs (SERC) and obtain legislative approval. Mr. Morton also expressed concern with the rule being too vague. Ms. Pontikes shared her perspective on FDA's position on lyophilization based on FDA's previous drafts of guidance.

Mr. Montgomery requested clarification regarding FDA's guidance on avoiding demonstratively complex medication preparation. Ms. Pontikes clarified that their guidance refers to products and not the process. Mr. Flynn requested clarification on whether any guidances on insanitary conditions addressed lyophilization. Ms. Pontikes answered that they did based on documented warnings. Mr. Flynn countered that FDA has not directly or officially addressed lyophilization.

Dr. Mikhael reminded the board that they are responsible for ensuring public safety from lyophilization and because the rule is silent about it, that is the purpose for the rule change. He recognized AnazaoHealth for the quality assurance they place on their lyophilization process and pointed out that since other companies may not have the same standard, AnazaoHealth could assist the board in determining the best way to update the rule.

Mr. Davis, a nuclear pharmacist and Director of Operations for AnazaoHealth, explained the company's process for lyophilization and affirmed their safety record. He agreed that some guidance may be needed but that the rule already outlines safety guidelines. Dr. Mikhael countered that the rule is silent on lyophilization, which needs to be addressed. Ms. Rivera added that proof or certification on competency is also needed. Mr. Wright pointed out that a process must be recorded to determine whether it is performed correctly. Mr. Davis argued that compounding is not the issue, but development of the drug is. He added that it is visually obvious after compounding whether it has worked. Ms. Rivera countered that though she understood some may find it visible, regulation is needed for those who aren't as familiar. Dr. Mikhael raised the point that AnazaoHealth's process is similar to cGMP's manufacturing standards and suggested taking this rule to the compounding committee to work together on a new proposal.

A motion was made by Mikhael to set a rule hearing for the Compounding Committee in February 2019. Motion passed unanimously. Dr. Mikhael suggested that AnazaoHealth Corporation send any documentation they want considered to board staff.

Dr. Michele Weizer, pharmacist and former board member, informed the board that she would also send documentation for the February rules hearing. The following documents were recommended for the board's review:

- guidance on insanitary conditions for 503A and 503B facilities
- an "inspection technical guide" from the FDA which assists inspectors and manufacturers on areas for concerns, areas for pitfalls, what to look for when surveying, etc.
- 483 letters from 2018 that reference insanitary conditions and lack of sterilization.

Jim Shepard, a former board inspector, recommended that the board review the 483 which was issued in April 2018. He further requested that they consider the points listed in the 483 during rulemaking.

Mary Crane, senior pharmacist with Inspection Services, commented that the aseptic process and filling for lyophilization is not the same. She also explained the importance of the fill volume

and why controls under lyophilization are needed, especially for higher volumes which introduce higher risk.

II. Reports

A. Chair's Report – Jeenu Philip, BPharm, Chair

Discussion:

1. Nominations for 2019 Officer Elections

A motion was made by Philip to nominate Dr. Mesaros for Chair. Motion passed unanimously.

A motion was made by Hickman to nominate Mr. Montgomery for Vice-Chair. Motion passed unanimously.

2. ASPL Update

Mr. Philip provided a brief overview of **his** attendance to ASPL, including presentations on DEA audits, DEA industry challenges, and standards of care relating to liability exposure. Mr. Philip also mentioned PBN presentations on DIR fees and contract terminations, a mock disciplinary hearing by the State of Arkansas, and a presentation on medication-assisting treatment. Dr. Mesaros commented on the diversity of presentations due to the organization's growth. He informed the board that the meeting is held annually in San Diego. Mr. Parrado added that the Board of Pharmacy from Idaho presented how they are reducing regulations while requiring pharmacists to take as many CEs as possible.

Mr. Philip informed the board that he also attended the NABP member forum in Illinois. He explained that the event is only for board members (no EDs or counsel involved) and is held every other year. He provided a brief overview of the meeting, which included discussion on advances in healthcare, penicillin testing, and elimination of the PIC/PDM. He suggested reserving time to discuss thoughts on the elimination of the PIC/PDM in Florida. Mr. Philip added that discussion at the NABP meeting also included expungement of disciplinary history, correlation between the number of times pharmacists take the NAPLEX and the likelihood of disciplinary action. Dr. Mesaros added that the meeting occurs in May and encouraged participation. He informed the board that they can contact the NABP office if they are interested in attending.

B. Executive Director's Report – C. Erica White, MBA, JD

Discussion:

1. Delegations to Executive Director

Ms. White asked the board if there were any other updates to delegation of authority for the executive director or the board office aside from the decision in the Tripartite Committee to delegate authority to the board staff pharmacist for CE Broker course

approval. The board had no further delegations.

2. 2019 Board of Pharmacy – Meeting Schedule

Ms. White reminded the board that the board meeting dates for 2019 have already been scheduled, approved, and locations have been set. She asked the board to let her know if there are any conflicts with those dates and times.

3. 2019 Board of Pharmacy – Proposed PCP Dates

Ms. White presented the proposed dates and the board to let her know if there are any conflicts. She pointed out that Mr. Wright had a conflict and asked for another board member to replace him, which could be done later.

4. Application Amendments / Changes

Ms. White informed the board that there will no longer be a universal application, but all applications will be standardized, which she will continue to provide updates on.

5. Criminal History Review Guidelines – Proposed Changes

Ms. White presented the proposed changes for the criminal history matrix, including the addition of categories. Mr. Flynn pointed out that the board has never delegated clearing felonies to the board offices and that it is important to review the proposals to determine if they agree. The following amendments were proposed:

- Category 3:
 1. Removing the “one time” occurrence and changing “more than one time” to “one or more times”
 2. Change time since incident from 5 years to 10 years
 3. Add “NOT involving drug possession or paraphernalia” to examples
- Category 4:
 1. Add “Drug possession and paraphernalia” to examples

A motion was made by Wright to approve the proposed criminal history matrix with the above amendments. Motion passed unanimously.

C. Attorney General's Report - David Flynn, Assistant Attorney General

1. Monthly Rules Report – November 2018

Mr. Harris gave a brief overview of the November 2018 Rules Report.

D. Investigative Services Report – Robert Difiore, Pharmaceutical Program Manager

Discussion:

Mr. Difiore provided a brief update on the second quarter inspection results as of December 10, 2018. Ms. Rivera commended Mr. Difiore and his team for their hard work.

III. General Business

A. Ratification Lists – A motion was made by Mikhael to approve the following list of ratifications. Motion passed unanimously.

1. Pharmacist (Licensure)
2. Pharmacist (Exam Eligibility)
3. Pharmacist Interns
4. Consultant Pharmacist
5. Nuclear Pharmacist
6. Pharmacy/Facilities
7. Registered Pharmacy Technicians
8. Nonresident Sterile Compounding
9. CE Providers
10. CE Courses

B. Approval of Minutes

1. October 2-3, 2018 Full Board Minutes – A motion was made by Bisailon to approve. Motion passed unanimously.
2. October 2, 2018 Legislative Committee Minutes – A motion was made by Mikhael to approve. Motion passed unanimously.
3. October 2, 2018 Compounding Committee Minutes – A motion was made by Mikhael to approve pending the amendment of attendance. Motion passed unanimously.
4. October 1-2, 2018 Rules Committee Minutes – A motion was made by Mesaros to approve. Motion passed unanimously.

10-minute break

C. Petitions for Declaratory Statement

1. Consulting Pharmacists Inc.; Reference: Rule 64B16-28.606, F.A.C., regarding whether out of state / remote pharmacies must have pharmacists with a Florida license to process medication orders for Florida. Mr. Anthony Ciccone was present and sworn in. Mr. Flynn voiced concern that state correctional institutions, Department of Corrections, and Department of Juvenile Justice are not present, so the board does not have all the facts to answer the question. Mr. Flynn advised that based on this concern and the possibility of this affecting a third party, a declaratory statement should not be issued. Dr.

Mikhael clarified that there are permits that allow pharmacies to ship into Florida and suggested that Mr. Ciccone review those permits. Ms. White offered to assist Mr. Ciccone in reviewing the online applications.

A motion was made by Mesaros to deny the declaratory statement. Motion passed unanimously.

IV. Public Comment

Mr. Jackson informed the board that HB 81 has been filed, which FPA supports, along with HB 59 and SB 104, which FPA is monitoring. He also thanked Ms. White for her valuable presentation at their Sarasota program. Lastly, Mr. Jackson pointed out a trend on direct and indirect numeration fees, which is creating a huge burden on small and family owned pharmacies. He was concerned that this will force many to close.

Mr. Philip revisited his topic on eliminating PDMs, as initially discussed in his chair's report, requesting input from the board. Dr. Hickman voiced concern of pharmacies becoming less safe if responsibility is removed from the PDM. Pros and cons were discussed regarding the possibility of removing PDMs.

Brian Conn, interested party, thanked Mr. Philip for addressing this subject. He proposed another example of the department imposing discipline on someone who is an owner of a Pharmacy and as a PDM, meaning they are disciplined twice for the same problem.

Mr. Montgomery brought up that when medical errors occur, pharmacies never benefit from the education imposed. He introduced a process that may benefit the entire pharmacy, which he will forward to board staff to place on the next agenda for discussion.

The meeting recessed at 4:44 p.m.

Wednesday, December 12, 2018 at 9:00 AM

Call to Order - The meeting was reconvened by the Chair, Mr. Philip, at 9:01 a.m.

Roll Call - Those present during the meeting included the following:

Board Members

Jeenu Phillip, BPharm, Chair
Jeffrey J. Mesaros, PharmD, JD, Vice-Chair
David Wright, BPharm
David Bisailon, Consumer Member
Jonathan Hickman, PharmD
Mark Mikhael, PharmD, Chair
Gavin Meshad, Consumer Member
Richard Montgomery, BPharm, MBA
Blanca R. Rivera, MPharm, MBA

Attorneys

Board Counsel:
David Flynn, Assistant Attorney General
Lawrence Harris, Assistant Attorney General

Department of Health Counsel:
Chris Jurich, Assistant General Counsel

Board Staff:

C. Erica White, Executive Director
Jessica Hollingsworth, Government Analyst II

Mr. Philip recognized Debra Glass, a former board member, students, Michael Jackson from FPA, Gary Daylen from FHSP, Mark Whitten, Bureau Chief, and Dr. Martha Brown from PRN for attending the meeting.

I. Committee Reports & Actions

Rules Committee – Jeffrey Mesaros, PharmD, JD, Chair

Mr. Harris provided a brief overview of the discussion on proposed changes to Rule 64B16-26.351, F.A.C.

A motion was made by Hickman to accept the committee recommendation for the proposed changes to Rule 64B16-26.351, F.A.C. Motion passed unanimously.

Mr. Harris provided a brief overview of the discussion on proposed changes to Rule 64B16-30.003, F.A.C. Discussion ensued regarding whether there should be citations for expired drugs. Mr. Whitten

clarified an inspector's need for the citation and how it assists them in using discretion and how this lightens the burden on the discipline process. He also reminded the board that citations can be disputed.

Edwin Bayo, Attorney, clarified that the violation is for dispensing the drug and reminded the board that they determined it should be standard practice to review their active shelf on a quarterly basis to remove outdated drugs. Mr. Harris suggested moving forward with Rule 64B16-28.110, F.A.C. and discussing the citations at the next meeting.

A motion was made by Bisaillon to accept the committee recommendation for the proposed changes to Rule 64B16-28.110, F.A.C. Motion passed unanimously.

A motion was made by Hickman to make Rule 64B16-28.110, F.A.C. a minor violation. Motion passed unanimously.

A motion was made by Hickman to accept the committee recommendation for the citation of failure to comply with pharmacist to registered pharmacist technician ratio for activities not involving sterile compounding; no injury to patient/customer in Rule 64B16-30.003, F.A.C. Motion passed unanimously.

A motion was made by Hickman to accept the committee recommendation for the above citation fine to be \$250. Motion passed unanimously.

Mr. Harris provided a brief overview of the committee discussion on Rule 64B16-26.400, F.A.C. He asked the board to delegate a board member for Mr. Harris to work with in developing the rule. Dr. Hickman clarified

A motion was made by Philip to delegate Dr. Mesaros to work with Mr. Harris on Rule 64B16-26.400, F.A.C. Motion passed unanimously.

Dr. Mesaros provided a brief overview of the committee discussion on the annual regulatory plan.

II. Applications Requiring Board Review

A. Pharmacist Intern Applications

1. Scronce, Caroline; 2202/26331 – Present and sworn in. A motion was made by Mikhael to approve. Motion passed unanimously.

B. Pharmacist Applications

1. Shearer, Samuel; 2201/51434 – A motion was made by Philip to approve. Motion passed unanimously.

C. Registered Pharmacy Technician Applications

1. Steward, Angela; 2208/73030 – A motion was made by Hickman to issue a continuance. Motion passed unanimously.
2. Scott, Jessica Roxanna; 2208/87592 – Present and sworn in. A motion was made by Meshad to issue a continuance, so Ms. Scott may obtain a PRN evaluation. Motion passed unanimously.
3. Carroll, Phyllis Anne; 2208/88315 – Present and sworn in. A motion was made by Meshad to issue a continuance, so Ms. Carroll may provide proof of a board-approved certification at the next meeting. Motion passed unanimously.

D. Pharmacy Permit Applications

1. Best Care Pharmacy, Inc.; 2205/25835 – Present and sworn in with Attorney, Edwin Bayo. A motion was made by Philip to approve. Motion passed with Mikhael and Rivera in opposition.
2. Best Care Pharmacy, Inc.; 2205/25836 – Present and sworn in with Attorney, Edwin Bayo. A motion was made by Philip to approve. Motion passed with Mikhael and Rivera in opposition.

III. Disciplinary Cases

A. Settlement Agreements

Recused Members: Debra Glass & David Wright

1. Patel, Pinkalkumar Navinchandra; PS 36548, Case #2018-08130, File #27334 **(\$1889.84)** – Present and sworn in with Attorney Brian Kahn. A motion was made by Mikhael to accept the settlement agreement. Motion passed unanimously.
2. Simons, Adam Michael; PS 55190, Case #2017-20948, File #48326 **(\$1658.06)** – Present and sworn in. A motion was made by Mikhael to reject the settlement agreement. Motion failed with Rivera, Bisailon, Hickman, Meshad in opposition. A motion was made by Hickman to reject the settlement agreement with the counter offer of removing the fine. Motion passed with Philip, Mesaros, Mikhael in opposition. The settlement agreement was accepted by Mr. Simons.

B. Determination of Waivers

The board, as appropriate, accepted unanimously the following motions: 1). The Department asks that you accept the investigative report into evidence for the purpose of imposing a penalty. 2). The Department asks that you find that the Respondent was properly served and waived the right to a formal hearing (either by failing to respond at all or timely). 3). The

Department asks that you adopt the findings of fact and conclusions of law as set forth in the Administrative Complaint and find that this constitutes a violation of the practice act.

Recused Members: Michele Weizer & Jeenu Philip

1. Webb, Charity Lynn; RPT 43523, Case # 2017-07055, File #45299 – The third motion listed above pertains to count one only. A motion was made by Mesaros to impose revocation. Motion passed unanimously.

Recused Members: Michele Weizer & Blanca Rivera

2. Haley, Dalton Gabriel; RPT 50922, Case #2017-19901, File #53140 – Present and sworn in. A motion was made by Wright to impose revocation. Motion passed unanimously.
3. Sasser, Toni L.; PSI 21365, Case #2018-05564, File #9105 – A motion was made by Bisaillon to impose revocation. Motion passed unanimously.

Recused Members: Jeenu Philip & Gavin Meshad

4. Tichinel, Suzanne; PS 44446, Case # 2017-01892, File #36399 – A motion was made by Mikhael to impose revocation. Motion passed unanimously.
5. Bergerstock, Leigh Ann; RPT 35991, Case # 2016-10633, File #36719 – A motion was made by Bisaillon to impose revocation. Motion passed unanimously.

Recused Members: Debra Glass & David Bisaillon

6. Jagasia, Kunal K.; PS 51465, Case #2017-07444, File #43994 – A motion was made by Wright to impose costs of \$4544.44 within one year of reinstatement of his license and suspension until respondent appears before the board and can demonstrate ability to practice with reasonable skill and safety to include at minimum a PRN evaluation and the right for the board to impose reasonable conditions of reinstatement at the time of appearance.

Recused Members: Michele Weizer & Jonathan Hickman

7. Fornaris, Yunesky Isreal; RPT 70602, Case #2017-04610, File #74766 – A motion was made by Bisaillon to impose revocation. Motion passed unanimously.

10-minute break

C. Voluntary Relinquishments

No Recused Members

1. Lurd's Inc. d/b/a Doctor's Choice Pharmacy; PH 27167, Case # 2018-01607, File #20338 – A motion was made by Mesaros to accept the voluntary relinquishment. Motion passed unanimously.

Recused Members: Michele Weizer & David Bisaillon

2. Kenny, Tashima Cheree; RPT 62519, Case # 2016-17809, File #52314 – A motion was made by Mesaros to accept the voluntary relinquishment. Motion passed unanimously.

Recused Members: David Wright & Debra Glass

3. Iqbal, Nadeem; PSI 18566, Case #2017-19413, File #6031 – A motion was made by Mikhael to accept the voluntary relinquishment. Motion passed unanimously.

Recused Members: Michele Weizer & Jonathan Hickman

4. Young, Edwin Patrick; PS 33965, Case #2016-20919, File #22974 – A motion was made by Meshad to accept the voluntary relinquishment. Motion passed unanimously.

Recused Members: Gavin Meshad & Debra Glass

5. Vital Life Healthcare, Inc.; PH 30574, Case #2017-21830, File #24071 – A motion was made by Bisaillon to accept the voluntary relinquishment. Motion passed unanimously.

D. Informals

The board, as appropriate, accepted unanimously the following motions: 1). The Department asks that you accept the investigative report into evidence for the purpose of imposing a penalty. 2). The Department asks that you find that the Respondent was properly served and requested an informal hearing. 3). The Department asks that you adopt the findings of fact as set forth in the Administrative Complaint. 4) The Department asks that you adopt the conclusions of law as set forth in the Administrative Complaint and find that this constitutes a violation of the practice act.

Recused Members: Mark Mikhael & Jeenu Philip

1. Bennett, Cody M.; PS 52401, Case #2017-20643, File #45614 – A motion was made by Bisaillon to impose costs of \$2698.82 within one year of reinstatement and suspension until respondent appears before the board and can demonstrate ability to practice with reasonable skill and safety to include at minimum a PRN evaluation and the right for the board to impose reasonable conditions of reinstatement at the time of appearance.

E. Prosecution Services Report – Chris Jurich, Assistant General Counsel

Mr. Jurich provided a brief update on the current caseload for the Prosecution Services Unit. He explained the increase of cases due to student loan defaults. A motion was made by Mikhael to allow PSU to continue to prosecute cases older than one year. Motion passed unanimously.

IV. Licensure Issues

A. Petition for Extension

1. Patel, Beena; PS 49946, Case #2017-01889, File #35305 – Present and sworn in. A motion was made by Mikhael to extend probation for 90 days. Motion passed unanimously.

B. Petition for Termination of Probation

1. Kassan, Douglas; PS 28503, Case #2006-42732, File #17530 – Present and sworn in. A motion was made by Meshad to deny. Motion passed unanimously.
2. Wickliffe Pharmaceuticals, Inc.; PH 22536, Case #2014-07670, File # – Present and sworn in. A motion was made by Philip to accept the petition. Motion passed unanimously.

V. Public Comment

Discussion:

Dr. Mikhael thanked the Chair, Mr. Philip for a great year or leadership.

Dr. Mesaros thanked the students for coming.

Dr. Hickman thanked everyone for a great learning experience with his first year on the board.

VI. Adjournment

The meeting adjourned at 2:08 p.m.